OCT 2 9 2004

K042903

510(k) SUMMARY SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories
540 Alder Dr.
Milpitas, CA 95035

Contact: Joy M. Sacmar
Tel: (408) 468-3053
Fax: (408) 468-3050

B. Device Trade Name: AutoSPECT®

Common Name:	Gamma Camera Systems
Classification Name:	Emission Computed Tomography System
Device Class:	21 CFR 892.1200, Class II
Product Code:	90 KPS

C. Date prepared: September 30, 2004

D. Predicate Device (s):

Manufacturer	Product Name	510(k) No.
ADAC Laboratories	AutoSPECT Plus with Instill Motion Correction	K992317

E. Intended Use:

AutoSPECT® produces images, which depict the three-dimensional distribution of radiopharmaceutical tracers in a patient. This software is intended to provide enhancements to gamma camera emission image processing by automating previously manual image processing functions, providing manual and automated motion correction, providing enhanced reconstruction algorithms that include resolution recovery, scatter correction, noise compensation, and attenuation correction via application of a transmission dataset.

F. Device Description:

AutoSPECT is a software application that produces images, which depict the three-dimensional distribution of radiopharmaceutical tracers in a patient via automatic or manual processing. One or more cardiac SPECT, gated SPECT, or MCD cardiac data sets may be processed automatically using AutoSPECT. Additionally, one or more non-cardiac SPECT, gated SPECT, or MCD data sets may be processed manually. AutoSPECT contains basic data-processing algorithms that have been cleared previously; in addition to enhanced data reconstruction algorithms that include scatter correction, resolution recovery, map-based attenuation correction, and OSEM (Astonish SPECT) reconstruction.

The AutoSPECT software option may be used on images from a gamma camera system that are DICOM 3.0 compatible. The following data sets may be used:

- Cardiac, brain, or other (bone, liver, etc.) SPECT datasets
- Gated SPECT datasets
- Vantage SPECT datasets
- SPECT-CT datasets
- Total Body SPECT datasets
- MCD and MCD-AC datasets

AutoSPECT provides the user three options for automatically processing cardiac datasets: AutoAll, Auto Recon, and Auto Reorient. Each option is described in greater detail in the software description section.

AutoSPECT also allows the user to process non-cardiac SPECT and MCD datasets. In this case, the operator manually positions the reconstruction limit lines to reconstruct transverse data sets. If necessary, the data set can be reoriented manually by positioning the azimuth, elevation, and twist lines to the desired locations.

In addition, the capability of processing groups of SPECT data sets in a batch mode fashion is provided. Once the operator has selected the datasets and determined the processing method, AutoSPECT processes the first dataset, followed by all remaining datasets without further interaction from the user.

AutoSPECT application runs on Microsoft Windows XP Professional environment. The minimum hardware requirements is listed:

- Intel x86/Pentium class processor > 1 GHz ;
- Graphics capability must meet or exceed 1280x1024 pixels with 32 bit pixel depth;
- 30 Gb of disk space (minimum);
- 512 Mb of DRAM (minimum);
- 10/100 BaseTX Ethernet interface;
- Port capable of supporting a dongle;
- CD drive- capable of reading and writing;
- 56Kbps modem (minimum)

G. Technological Comparison:

AutoSPECT and the predicate, AutoSPECT Plus with InStill Motion Correction, have similar indication for use, utilize similar methods for motion correction, reconstruction, and display of images. AutoSPECT like the predicate device also has the tools for automated and manual processing of images. AutoSPECT will provide new enhanced data reconstruction algorithms that include scatter correction, resolution recovery, map-based attenuation correction, and OSEM (Astonish SPECT) reconstruction. The similarities and differences between AutoSPECT and the predicate device are described in detail in predicate comparison section of this pre-market notification.

H. Conclusion:

AutoSPECT is substantially equivalent to the following predicate device, AutoSPECT Plus with InStill Motion Correction (K992317) based on similar intended use and technological comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2004

ADAC Laboratories
c/o Ms. Denise Klinker
Regulatory Affairs Specialist
Underwriters Laboratories Inc.®
1655 Scott Blvd.
SANTA CLARA CA 95050

Re: K042903
Trade/Device Name: AutoSPECT®
Regulation Number: 21 CFR §892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: October 14, 2004
Received: October 15, 2004

Dear Ms. Sacmar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042903

Device Name: AutoSPECT

Indications For Use:

AutoSPECT® produces images, which depict the three-dimensional distribution of radiopharmaceutical tracers in a patient. This software is intended to provide enhancements to gamma camera emission image processing by automating previously manual image processing functions, providing manual and automated motion correction, providing enhanced reconstruction algorithms that include resolution recovery, scatter correction, noise compensation, and attenuation correction via application of a transmission dataset.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042903